UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/519,943	12/29/2004	Martijn Gipmans	12810-00140-US	5073

23416 7590 08/21/2007
CONNOLLY BOVE LODGE & HUTZ, LLP
P O BOX 2207
WILMINGTON, DE 19899

EXAMINER	
BAGGOT, BRENDAN O	

ART UNIT	PAPER NUMBER
1638	

MAIL DATE	DELIVERY MODE
08/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/519,943	GIPMANS ET AL.	
	Examiner	Art Unit	
	Brendan O. Baggot	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Restriction / Election

1. The text of those sections of title 35 U.S.C. not included in this action can be found in a prior Office action.

2. The Office acknowledges the receipt of Applicant's Response filed 6/1/07. Claims 12-30 are newly added. Claims 12-30 are pending and examined.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The claim objections under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim e.g. "any of. . ." are withdrawn in light of Applicant's amendments.

5. The prior rejections under 35 U.S.C. §112, second paragraph are hereby withdrawn in light of applicant's amendments.

Claim Rejections - 35 U.S.C. §112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 23-25 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which

the applicant regards as the invention.

11. In Claims 23-25, it is unclear what is being retained in the derived product of ". . . derivatives . . .".

Claim Rejections - 35 USC § 112, 1st, paragraph, written description

6. Claims 12, 14-16, 19-23, 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The *Wands* court set forth the enablement balancing test:

> Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described by the court in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). *Wands* states at page 1404, "Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the 'claims.

M.P.E.P. § 2164.01(a).

This rejection is modified and maintained for reasons of record set forth in the Official action mailed 12/1/06. Applicant's arguments filed 6/1/07 have been fully considered but are deemed not persuasive.

The rejection over 60% sequence identity has been modified to 90% sequence identity.

Applicant traverses primarily that the specification provides a correlation between

structure (the gene itself as set forth in SEQ ID NO: I, which encodes SEQ ID NO: 2) and the function of the gene, i.e. modifying oil content. (Response, page 9).

This is not persuasive because while Applicant has correlated the TAG modifying activity with SEQ ID NO: I which encodes SEQ ID NO: 2, applicant has not made such a correlation to sequences with 90% sequence identity. A description of a single species of a genus, without any genus identifying structural characteristics, is not adequately described. A 10% change in a protein with 655 amino acids represents 65 amino acid changes. Given that it is well known that most active sites comprise no more than 4-8 amino acids, a change of 65 amino acids is quite large. Given the 20 known amino acids and 65 changes possible, the number of permutations encompassed by 65 changes is 65^{20} = 6,500,000,000,000,000,000,000 different species. Also, applicant has not described the active site.

Applicant traverses primarily that Amgen is inapposite because the specification discloses a purified and isolated DNA sequence (SEQ ID NO: I) and the polypeptide encoded by this gene (SEQ ID NO: 2), thereby providing a description of the DNA itself and the polypeptide.

This is not persuasive because description of SEQ ID NO: 1 encoding SEQ ID NO: 2 does not describe a representative number of all the variations or the structural features common to members of the genus encompassed by 90% sequence identity. As stated above, 65 amino acid changes is quite large.

Applicant traverses primarily that Amgen is inapposite because the nucleic acid sequence is not solely defined by function or by a general method for identifying or

obtaining a gene. Rather, the actual sequence is disclosed in the specification has been correlated to function.

This is not persuasive because a description of SEQ ID NO: 1 encoding SEQ ID NO: 2 function or by a general method for identifying or obtaining a gene IS NOT a description of even one additional species. Applicant has not identified the characteristics required to identify all the variations or the structural features common to members of the genus encompassed by TEP proteins. Applicant has not even identified the function of the protein. The skilled artisan would not believe applicant was in possession of the claimed invention.

The Rejection Has Been Modified.

Applicants' claims are broadly drawn to transforming any plant with any sequence from any species of any length having as little as 90% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2, or variants thereof, having non-exemplified and unspecified activity, any vector, cassette, plant organism, tissue, organ part, cell, or propagation material containing said sequence, any plant transformed therewith, any seeds comprising any sequence having as little as 90% sequence identity to SEQ ID NO: 1. The claims also encompass SEQ ID NO: 1 and SEQ ID NO: 2 homologs from other species. The claims also encompass SEQ ID NO: 2 homologs from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known.

Applicants describe SEQ ID NO: 1 and SEQ ID NO: 2. (See the sequence listing).

Applicants do not describe sequences which are merely 90% identical to SEQ ID NO: 1 or SEQ ID NO: 2, the crystal structure of SEQ ID NO: 2, or the allosteric or active sites of SEQ ID NO: 2. Applicants fail to even teach the reaction catalyzed by the enzyme with the sequence of SEQ ID NO: 2.

Applicants fail to describe a representative number of variants of SEQ ID NO: 2 or other sequences. Applicants only describe SEQ ID NO: 2. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of SEQ ID NO: 2. Applicant's don't even describe the reaction catalyzed by SEQ ID NO: 2 let alone the common structural features the genus of variants of SEQ ID NO: 2 or 60% identical to SEQ ID NO: 2 or even a representative number of species. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*.

Furthermore, given the lack of description of the necessary elements essential for variants of SEQ ID NO: 2 or 60% identical to SEQ ID NO: 2, it remains unclear what features identify said genus of variants of SEQ ID NO: 2 or 60% identical to SEQ ID NO: 2. Since the genus of variants of SEQ ID NO: 2 or 60% identical to SEQ ID NO: 2 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

Moreover, sequences that are 60% complementary to SEQ ID NO: 2 encompass naturally occurring allelic variants, mutants of SEQ ID NO: 2, as well as sequences encoding proteins having no known oil profile modifying activity, of which Applicant is not in possession. Accordingly, the specification fails to provide an adequate written description to support the genus of sequences 60% sequence identical to SEQ ID NO: 2

as encompassed by the percent identity language as set forth in the claims. (See Written Description guidelines published in Federal Register/Vol. 66, No.4/Friday, January 5, 2001/Notices: p.1099-1111).

The Federal Circuit has clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id. Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." Id.

Finally, the court held:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP Section 2163, page 174 of Chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

> [T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for

written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. *See* The Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Therefore, the claims are not adequately described.

Claim Rejections - 35 U.S.C. §112, first paragraph, enablement

7. Claims 12, 14-16, 19-23 and 28 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NO: 1 and SEQ ID NO: 2 and yeast and *Arabidopsis* transformed therewith, yeast with increased triacylglycerol and *Arabidopsis* with increased total oil of unspecified character, does

not reasonably provide enablement for sequences which are 90% sequence identical to SEQ ID NO: 1 or 2 or variants thereof or their use to alter oil in transformants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

This rejection is modified and maintained for reasons of record set forth in the Official action mailed 12/1/06. Applicant's arguments filed 6/1/07 have been fully considered but are deemed not persuasive.

The rejection over 60% sequence identity has been modified to 90% sequence identity.

Applicant traverses primarily that since the present claims are drawn to methods and expression cassettes where a polypeptide from yeast or a nucleic acid encoding the polypeptide when expressed transgenically results in increased oil content in plants, the claims do not encompass sequences from any species. (Response, page 10).

This is deemed not persuasive because the 65 amino acid changes encompassed by a 10% sequence identity difference almost certainly does encompass functionally similar yet unknown proteins from different species.

Applicant traverses primarily that in light of the present claims, the quantity of experimentation would not be very large to identify homologs, clone the homologs, do enzyme assays to confirm enzyme activity, select the homologs with high activity, transform plants, and screen for transformants with high activity. (Response, page 10).

This is deemed not persuasive because – as explained above – the 65 amino acid changes encompassed by 90% sequence identity would require the screending of a very large number of sequences.

Applicant traverses primarily that the instant type of screening and testing is "routine" because the specification provides guidance on identifying, isolating, and analyzing functional equivalents or homologs of the genes of the invention and one skilled in the art would recognize that screening and testing for enzyme activity in microorganisms and plant species is routine and is not undue experimentation. (Response, page 10-11).

This is deemed not persuasive because the number of different sequences encompassed by 65 amino acid changes is so large that to screen through such a large number of sequences to determine which ones have function would be undue experimentation which is not routine.

Applicant traverses primarily that the instant type of screening and testing is "routine" because transformation and regeneration of plants is well known by one of ordinary skill in the art. (Response, page 10-11).

This is deemed not persuasive because t the number of different sequences encompassed by 65 amino acid changes is so large that to screen through such a large number of sequences to determine which ones have function would be undue experimentation which is not routine.

Applicant traverses primarily that the instant type of screening and testing is "routine" because assays for determining activity, describe transformation of yeast and

plants and screening of the transformants for activity were taught in the specification. (Response, page 10-11).

This is deemed not persuasive because the number of different sequences encompassed by 65 amino acid changes is so large that to screen through such a large number of sequences to determine which ones have function would be undue experimentation which is not routine.

Applicant traverses primarily that because the specification provides detailed guidance, the specification teaches Examples, screening and testing is "routine" t to confirm enzyme activity, working examples showing activity were provided, the unpredictability alleged by the Examiner is overcome. (Response, page 11).

This is deemed not persuasive because the number of different sequences encompassed by 65 amino acid changes is so large that to screen through such a large number of sequences to determine which ones have function would be undue experimentation which is not routine.

Applicant traverses primarily that Enzo is inapposite to the present application because Antisense technology is *totally* different than the gene expression of the present invention. (emphasis added). (Response, page 11).

This is deemed not persuasive because sense and antisense expression are essentially identical up to and through transcription. In both cases, DNA polymerase duplicates the gene and RNA polymerase transcribes it. The Office agrees that antisense is different from sense expression.

Applicant traverses primarily that Enzo is inapposite to the present application because Applicants have demonstrated that when the gene is disrupted the activity is also modified and thus have provided actual working examples and data demonstrating the method and use of the gene and expression cassettes as presently claimed, not just a plan or invitation to experiment.

This is deemed not persuasive because applicants have provided working examples of only SEQ ID NO: 1 encoding SEQ ID NO: 2. The claims encompass many sequences which are different from SEQ ID NO: 1. Many of the claimed sequences likely have no function whatsoever because of nonconservative changes to the amino acid.

The Enablement Rejection Has Been Modified.

Applicants' claims are broadly drawn to transforming plants with any sequence having as little as 90% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2, or variants thereof, having non-exemplified and unspecified activity, any vector, cassette, plant organism, tissue, organ part, cell, or propagation material containing said sequence, any plant transformed therewith, any seeds comprising any sequence having as little as 90% sequence identity to SEQ ID NO: 1. The claims also encompass SEQ ID NO: 1 and SEQ ID NO: 2 homologs from other species. The implication is that there is a gene and a protein other than that disclosed which exists in nature, but the structure thereof is not known.

Applicants teach SEQ ID NO: 1 and SEQ ID NO: 2. (See the sequence listing).

Applicants do not teach sequences which are merely 90% identical to SEQ ID NO: 1 or SEQ ID NO: 2, variants of SEQ ID NO: 1 or SEQ ID NO: 2, the crystal structure of SEQ ID NO: 2, or the allosteric or active sites of SEQ ID NO: 2. Applicants fail to even teach the reaction catalyzed by the enzyme with the sequence of SEQ ID NO: 2.

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art, balanced only against the high level of skill in the art as discussed above, undue trial and error experimentation would be required to practice the claimed invention, and therefore the invention is not enabled throughout the broad scope of the claims.

The Breadth Of The Claims

The claims are broadly drawn to and encompass transforming plants with any any sequence of any length from any species having as little as 60% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2 having non-exemplified and unspecified activity, any vector, cassette, plant organism, tissue, organ part, cell, or propagation material containing said sequence, any plant transformed therewith, any seeds comprising any sequence having as little as 60% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2 over unspecified portions and having exemplified and non-exemplified activity. The claims are further drawn to "variants" of SEQ ID NO: 1 and 2.

The broad language expressly includes sequences with less than 100% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2 from any species with any sequence having any function, including sequences encoding proteins with no total oil increasing activity.

With regard to sequences having less than 100% sequence identity and sequences, the breadth of these claims encompasses unspecified base substitutions, deletions, additions, insertions, and combinations thereof without retaining function or with an inadequate function.

The Unpredictability of the Art and the State of the Prior Art

Modifying plant oil content is well-known to be unpredictable.

Post-Beittenmiller, et al., (1989) Plant Cell 1:889-899) teach that alteration of lipid biosynthesis is unpredictable. Post-Beittenmiller postulated that transgenic plants overexpressing Acyl carrier protein (ACP) with a transit peptide under the control of the rubisco small subunit promoter would alter lipid biosynthesis. Post-Beittenmiller et al found that while ACP protein levels in transgenic plants were expressed at a 2-3 fold higher level than endogenous ACPs, lipid analyses of the transformed plants indicated that the increased ACP levels caused no significant alterations in leaf lipid biosynthesis. (*See* the abstract).

Stephanopoulos, et al., (1993) Tibtech 11:392-396) teaches that manipulation of enzymatic reactions that are part of a product-forming pathway has led to failed or marginally successful results in fatty acid biosynthesis despite the success of others using similar approaches. (page 393, right column, 1st paragraph). Stephanopoulos continues that inserting just any gene in a pathway, without first determining the key branch points is not a rational experimental design and that the skilled artisan should first determine the critical or principal nodes which control metabolic flux through the

pathway so as to favor the desired product and to disfavor the unwanted side products. (*See* Figure 2, abstract, pages 392-396).

There is abundant prior art to suggest that identifying proteins via percent identity alone is difficult, unpredictable and unsuccessful.

It is well established that sequence similarity is not sufficient to determine functionality of a coding sequence. *See* the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar function's" (the last sentence of the first paragraph of page 2484). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph).

Applicants' failure to teach the enzymatic activity of YJR098c, when coupled with the teachings of Stephanopoulos and Post-Beittenmiller, and the lack of data beyond a mere statement of altered oil levels, supports an additional inference in the mind of the skilled artisan that even if some weak data showing alterations of oil levels was obtained, these data are likely little more than a plan or invitation for those of skill in the art to experiment using the technology.

Working Examples

The specification has no working examples of sequences which are 60% identical to SEQ ID NO: 1 or 2, no working examples of any protein with demonstrated

total oil content increasing activity, and no working examples of transgenic plants or seeds therefrom with demonstrated total oil content increasing activity.

The specification has no working examples of transforming plants with any sequence having as little as 60% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2 having non-exemplified and unspecified activity, any vector, cassette, plant organism, tissue, organ part, cell, or propagation material containing said sequence, any plant transformed therewith, any seeds comprising any sequence having as little as 60% sequence identity to SEQ ID NO: 1 or SEQ ID NO: 2 over unspecified portions and having exemplified and non-exemplified activity.

The specification does provide working examples of YJR098c yeast knockouts with reduced triacylglycerol (*See* Example 1, page 27-28), YJR098c expressing yeast with increased triacylglycerol (*See* Example 2, page 28-30), and transgenic plants expressing YJR098c with "significantly higher total oil content in transgenic lines." (*See* Example 3, page 30-31).

Guidance in the Specification

The specification, while suggesting the use of the SEQ ID NO: 1, did not provide significant guidance on how to overcome art recognized problems in identifying homologs based on sequence identity alone. The specification provided no guidance on overcoming art-recognized problems with natural plant mechanisms which ensure homeostasis.

The specification also did not provide significant guidance on how to overcome art recognized problems in identifying homologs having 60% sequence identity, variants, mutants and alleles of SEQ ID NO: 1,2. It is well established that sequence similarity is not sufficient to determine functionality of a coding sequence. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar function's" (the last sentence of the first paragraph of page 2484. Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph).

Accordingly, one skilled in the art cannot make and use sequences having at least 60% sequence identity with SEQ ID NO:1 without improperly extensive and undue experimentation. Without sufficient guidance, determination of what portions of SEQ ID NO: 2 would tolerate changes, additions, insertions, or deletions and without guidance on how to overcome the problems seen in expressing oil pathway proteins in transgenic plants, it is unpredictable and the experimentation left to those skilled in the art is unnecessarily and improperly extensive and undue. *See In re Wands*, 858 F.2d 731,8 USPQ2nd 1400 Fed. Cir, 1988)

Therefore, given the breadth of the claims; the lack of guidance and working examples; the unpredictability in the art; and the state-of-the-art, balanced only against the high level of skill in the art as discussed above, undue trial and error experimentation would be required to practice the claimed invention, and therefore the

invention is not enabled throughout the broad scope of the claims.

Accordingly, the claims are not enabled.

Comment

SEQ ID NO: 1 and SEQ ID NO: 2 were known in the art. Ramezani, et al.(Identity Nuc. Database. ACCESSION Z49598 Y13136, locus SCYJR098C, 11 August 1997) is 92.3% identical at the nucleic acid level and 100% identical at the amino acid level. Ramezani was cited but not submitted with Applicant's IDS.

Also, Bauer, et al (GenEBML Database Accession No. AX594852, 14 February 2003) teaches a sequence (Bauer's SEQ ID NO: 506) which is 100% identical to Applicant's SEQ ID NO: 2.

Despite Ramezani and Bauer, Lichtenberg (2005) Yeast 22:1191-1201) teaches that the function of YJR098C is unknown as late as 2005. (Id. @ Table 2, page 1198).

8. Claims 13, 17-18, 24, 25, 27 and 29-30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brendan O. Baggot whose telephone number is 571/272-5265. The examiner can normally be reached on Tuesday through Thursday, 10:00 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on 571/272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

bob

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER